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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/868,832 06/21/01 HIROTA

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HM12/1029

EXAMINER

FORMAN, B

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

10/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/868,832

Applicant(s)

HIROTA ET AL.

Examiner

BJ Forman

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-8 are indefinite for the recitation "spots based on capture solutions arranged on a base plate" because "based on" is not standard terminology used in the art and therefore one of skill in the art would not be appraised of the scope of the claim. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The phrase "based on" in claims 1-8 is used by the claim to mean "consisting of," while the accepted meaning is "positioned upon." It is suggested that the claims be amended to clearly define the invention e.g. replace "based on" with "consisting of".

b. Claims 1-8 are indefinite for the recitation "said capture solutions each of which specifically reacts with a specimen and each of which is used to obtain information on a structure" because "reacts" and "structure" both lack proper antecedent basis in the "capture" solution. It is suggested that the claims be amended to provide proper antecedent basis e.g. replace "reacts with" with "captures a structure within".

c. Claims 1-8 are indefinite for the recitation "each of which is used to obtain information on a structure" because it is unclear how the recitation of a use for the capture solution further limits the biochip apparatus. It is suggested that the claims be amended to

Art Unit: 1655

describe the structural limitations of the biochip as taught in the specification e.g. poly-L-lysine and DNA fragments (page 14, line 26-page 15, line 5).

d. Claim 2 is indefinite for the recitation "which have different spot sizes on said base plate respectively" because "respectively" is a non-specific relational term and therefore the relationship between "spot sizes" and "base plate" is undefined. It is suggested that the claim be amended to define the relationship e.g. delete "respectively".

e. Claim 2 is indefinite for the recitation "are formed for captures of an identical type" because the recitation is a method step of forming and it is unclear how the method step further limits the biochip apparatus. It is suggested that the claim be amended to describe the structural limitations as taught in the specification e.g. replace "are formed for" with "wherein the capture solution". The recitation is further indefinite because "an identical type" lacks proper antecedent basis in Claim 1 which recites "a structure". It is suggested that Claim 2 be amended to provide proper antecedent basis e.g. replace "type" with "structure of said specimen" (page 8, lines 5-12).

f. Claims 3 and 4 are indefinite in Claim 3 for the recitation "a plurality of said spots are formed" because the recitation is a method step of forming and it is unclear how the method step further limits the biochip apparatus. It is suggested that the claim be amended to describe the structural limitations of the biochip as taught in the specification e.g. delete "are formed".

g. Claims 3 and 4 are indefinite in Claim 3 for the recitation "a capture per unit area immobilized in each of said spots" because "capture" and "immobilized" both lack proper antecedent basis in the preamble of Claim 3. It is suggested that Claims 3 and 4 be amended to provide proper antecedent basis e.g. after "capture" insert "solution" and replace "immobilized" with "arranged".

h. Claim 4 is indefinite for the recitation "which have different amounts.....on said base plate respectively" because "respectively" is a non-specific relational term and therefore

Art Unit: 1655

the relationship between "amounts" and "base plate" is undefined. It is suggested that the claim be amended to define the relationship e.g. delete "respectively".

i. Claim 4 is indefinite for the recitation "are formed for captures of an identical type" because the recitation is a method step of forming but it is unclear how the method step further limits the biochip apparatus. It is suggested that the claim be amended to describe the structural limitations as taught in the specification e.g. replace "are formed for captures" with "wherein the capture solutions are". The recitation is further indefinite because "an identical type" lacks proper antecedent basis in Claim 3. It is suggested that Claim 4 be amended to provide proper antecedent basis e.g. replace "type" with "structure of said specimen" (page 8, lines 5-12).

j. Claim 5 is indefinite for the recitation "are formed at an identical spot formation position" because the recitation is method step of forming but it is unclear how the method step further limits the biochip apparatus. It is suggested that the claim be amended to describe the structural limitations as taught in the specification e.g. replace "are formed at" with "have". The recitation is also indefinite because "identical" is a relational term but it is unclear what relationship is being described i.e. it is unclear to what the claimed "position" is identical. The recitation is further indefinite because "spot formation position" lacks proper antecedent basis in the preamble of the claim. It is suggested that the claim be amended to provide proper antecedent basis and define the identify relationship e.g. replace "are formed at an" with "have a" and delete "identical" or define the relationship in which the position is "identical".

k. Claims 6 and 7 are indefinite in Claim 6 for the recitation "substantially circular configuration" because "substantially" is a quantitative term which requires definition or criteria for determining. It is suggested that Claim 6 be amended to define or recite criteria for determining "substantially circular configuration" e.g. replace ", and" with "wherein said configuration comprises" and delete "said substantially circular configuration is".

Art Unit: 1655

l. Claim 7 is indefinite for the recitation "and area in which said spot is not deposited" because "area" and "deposited" both lack proper antecedent basis in Claim 6. It is suggested that Claim 7 be amended to provide proper antecedent basis e.g. replace "and area" with "said base plate" and replace "deposited" with "arranged".

m. Claim 7 is indefinite for the recitation "with respect to an inspection effective area" because the recitation lacks proper antecedent basis in Claim 6. It is suggested that Claim 7 be amended to provide proper antecedent basis e.g. replace "with respect to an inspection effective area on" with "to" and after "said base plate" insert "in which said spot is arranged".

n. Claim 8 is indefinite for the recitation "are formed by means of an ink-jet system" because the recitation is method step of forming but it is unclear how the method step further limits the biochip apparatus. It is suggested that the claim be amended to describe the structural limitations as taught in the specification e.g. replace "are formed by means of an ink-jet system" with "have a diameter of several hundred μm " (page 21, lines 19-24).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-5 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Felder et al. (U.S. Patent No. 6,232,066 B1, filed 2 July 1998). The functional limitations recited in the

Art Unit: 1655

claims are not given any patentable weight because, as stated above, it is unclear how the functional recitations further limit the structural limitations.

Regarding Claim 1, Felder et al. disclose a biochip comprising a large number of spots arranged on a base plate (Column 4, line 63-Column 18) obtained by supplying a plurality of types of capture solutions (i.e. anchors) onto said base plate each of which specifically reacts with a structure of a specimen (Column 7, lines 46-48) and wherein the plurality of spots have different spot sizes (Column 8, lines 52-56).

Regarding Claim 2, Felder et al. disclose the biochip of Claim 1 wherein said capture solutions capture are for capture of an identical type e.g. nucleic acid hybridization (Column 6, lines 52-67).

Regarding Claim 3, Felder et al. disclose a biochip comprising a large number of spots (i.e. bar-code) arranged on a base plate (Column 8, line 29-38) obtained by supplying a plurality of types of capture solutions (i.e. anchors) onto said base plate each of which specifically reacts with a structure of a specimen (Column 7, lines 46-48) and wherein the amount of capture solution per unit area of each spot differs i.e. each bar-code within the area (i.e. spot) comprises a different pattern and therefore a different amount (Column 8, lines 16-28).

Regarding Claim 4, Felder et al. disclose the biochip of Claim 3 wherein said capture solutions are for capture of an identical type e.g. nucleic acid hybridization (Column 6, lines 52-67).

Regarding Claim 5, Felder et al. disclose a biochip comprising a large number of spots arranged on a base plate (Column 4, line 63-Column 18) obtained by supplying a plurality of types of capture solutions (i.e. anchors) onto said base plate each of which specifically reacts with a structure of a specimen (Column 7, lines 46-48) wherein the spots are composed of different types of captures (i.e. different oligonucleotide anchors) formed at an identical spot formation position (Column 2, lines 49-62).

Art Unit: 1655

Regarding Claim 8, Felder et al. disclose the biochip of Claim 1 wherein the spots are formed with an in-jet system (Column 13, lines 23-34).

5. Claims 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyldig-Nielsen et al. (U.S. Patent No. 6,280,946 B2, filed 3 August 1999).

Regarding Claim 3, Hyldig-Nielsen et al. disclose a biochip comprising a large number of spots arranged on a base plate obtained by supplying a plurality of types of capture solutions (RNA solutions) onto said base plate, each of which specifically reacts with a structure of a specimen wherein the amount of capture per unit area of said spots differs (Column 25, lines 36-48).

Regarding Claim 4, Hyldig-Nielsen et al. disclose the biochip of Claim 3 wherein the spots are for capture of an identical type of structure i.e. PNA probes (Column 25, lines 63-66).

Regarding Claim 5, Hyldig-Nielsen et al. disclose a biochip comprising a large number of spots arranged on a base plate obtained by supplying a plurality of types of capture solutions (RNA solutions) onto said base plate, each of which specifically reacts with a structure of a specimen wherein the spots are composed of different types of captures (i.e. different RNAs) and are at identical spot formation pattern (Column 26, lines 16-41 and Fig. 1-5).

Regarding Claim 6, Hyldig-Nielsen et al. disclose a biochip comprising a large number of spots arranged on a base plate obtained by supplying a plurality of types of capture solutions (RNA solutions) onto said base plate, each of which specifically reacts with a structure of a specimen wherein the spots are circular i.e. the ratio of a major to minor axis is not less than .9 and not greater than 1.1 (Column 26, lines 16-41 and Fig. 1-5).

6. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (U.S. Patent No. 5,807,522, issued 15 September 1998).

Regarding Claim 5, Brown et al. disclose a biochip comprising a large number of spots based on capture solutions arranged on a base plate, obtained by supplying onto said base plate a plurality of types of capture solutions each of which specifically reacts with a specimen wherein said spots are composed of different types of captures (i.e. a different analyte-specific reagent) and are formed at an identical spot formations position (Column 3, lines 23-34).

Regarding Claim 6, Brown et al. disclose a biochip comprising a large number of spots arranged on a base plate obtained by supplying a plurality of types of capture solutions (RNA solutions) onto said base plate, each of which specifically reacts with a structure of a specimen and are at identical spot formation pattern (Column 3, lines 23-34) wherein the spots are circular (i.e. they have a defined diameter) wherein the ratio of a major to minor axis is not less than .9 and not greater than 1.1 (Column 8, lines 48-63).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent No. 5,807,522, issued 15 September 1998) in view of Fisher (U.S. Patent No. 6,232,072, filed 15 October 1999).

Art Unit: 1655

Regarding Claim 7, Brown et al. teach a biochip comprising a large number of spots based on capture solutions arranged on a base plate, obtained by supplying onto said base plate a plurality of types of capture solutions each of which specifically reacts with a specimen wherein said spots are composed of different types of captures (i.e. a different analyte-specific reagent) (Column 3, lines 23-34) but they do not teach a ratio of the area having a spot to not having a spot. However, Fisher teaches a similar biochip comprising a large number of spots based on capture solutions arranged on a base plate obtained by supplying onto said base plate a plurality of types of capture solutions each of which specifically reacts with a specimen (Column 3, lines 27-32) wherein the size, shape and arrangement of the spots can be adjusted as desired to form patterns on the base plate (Column 10, lines 1-9 and 32-49) to thereby determine capture characteristics by location on the pattern (Column 10, lines 42-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the spot pattern of Brown et al. and to arrange the spots in a zigzag pattern wherein the non-deposition area to deposition area ratio is not more than 9% thereby providing a pattern wherein structure-specific capture is easily determined by determining its location within the pattern for the obvious benefit of facilitating detection of structure-capture interaction as taught by Fisher (Column 10, lines 42-47).

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this


Application/Control Number: 09/868,832


Page 10

Art Unit: 1655

application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
October 26, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600